PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 11827PC2-MLE/AKB	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. **PCT/AU2004/000354**	International filing date *(day/month/year)* 19 March 2004	Priority date *(day/month/year)* 20 March 2003
International Patent Classification (IPC) or national classification and IPC **Int. Cl.** [7] A61M 5/315 A61M 5/50		
Applicant UNITRACT SYRINGE PTY LTD et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. [X] *(sent to the applicant and to the International Bureau)* a total of 4 sheets, as follows:
      - [ ] sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      - [ ] sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. [ ] *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - [X] Box No. I Basis of the report
   - [ ] Box No. II Priority
   - [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - [ ] Box No. IV Lack of unity of invention
   - [X] Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - [X] Box No. VI Certain documents cited
   - [ ] Box No. VII Certain defects in the international application
   - [ ] Box No. VIII Certain observations on the international application

Date of submission of the demand 27 July 2004	Date of completion of the report 7 March 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **MATTHEW FORWARD** Telephone No. (02) 6283 2606

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/000354

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1 (b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

☐ the international application as originally filed/furnished

☒ the description:

pages **1-3, 5-10** as originally filed/furnished
pages* **4** received by this Authority on **27 July 2004** with the letter of **27 July 2004**
pages* received by this Authority on with the letter of

☒ the claims:

pages as originally filed/furnished
pages* as amended (together with any statement) under Article 19
pages* **11-13** received by this Authority on **27 July 2004** with the letter of **27 July 2004**
pages* received by this Authority on with the letter of

☒ the drawings:

pages **1/8 -8/8** as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages
☐ the claims, Nos.
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages
☐ the claims, Nos.
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-22	**YES**
	Claims		**NO**
Inventive step (IS)	Claims	1-22	**YES**
	Claims		**NO**
Industrial applicability (IA)	Claims	1-22	**YES**
	Claims		**NO**

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1 US 5167641 (SCHMITZ)
D2 US 5984898 (GARVIN)
D3 US 6039713 (BOTICH et al)
D4 FR 2794650 (BRUNEL)
D5 WO 2001/030427 (COMPAGNIE PLASTIC OMNIUM)
D6 EP 0347742 (VENTURINI)
D7 WO 1993/025257 (ADAMS)
D8 US 6527742 (MALENCHEK)

The present application defines a spring retainer for a syringe (claim 1) and a syringe (claim 7), characterised by the spring being "releasably maintained" in a compressed state by two body members until the spring is decompressed by rotational disengagement of the body members (claim 1) or disengagement of the body members (claim 7). A retractable needle is "retracted" into the body of the syringe by the decompression of the syringe.

Documents D1 to D3 disclose a needle kept in compression by the action of a "housing", until the action of the plunger acts to release the spring.

Documents D4 and D5 disclose needle shields positioned around a syringe. The syringe is retracted into the shield after the plunger has expelled the contents as a result of an interaction between the plunger and a "housing" located on the shield. The spring is released from a compressed state via an action similar to that in the present claims.

Documents D6, D7 and D8 recite syringes wherein the needle is retracted due to decompression of a spring. In these documents the plunger compresses the spring as it expels the contents of the syringe. A spring that remains compressed until required to decompress is not suggested by these documents

None of these documents disclose disengagement of first and second body members to allow decompression of a spring and retraction of a retractable needle. Claims 1 to 22 satisfy Articles 33(2) to 33(4) of the PCT.

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Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date (valid claim) *(day/month/year)*
P,X US 6569115	27 May 2003	20 March 2000	28 August 1997

This document recites a needle device within a housing. The spring remains compressed until the contents of the syringe have been expelled, the spring being released by completion of the plunger stroke. Claims 1 to 22 are novel and inventive in view of this document.

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure *(day/month/year)*	Date of written disclosure referring to non-written disclosure *(day/month/year)*

end 41 of barrel 40, and comprises first body member 70 and second body member 80 that co-operate to house and maintain spring 90 in the initial compressed state shown in FIG. 1. Syringe 10 also comprises seal 11 located on plunger 20, which prevents leakage fluid between plunger 20 and internal wall 42 of barrel 40.

Retractable needle 50 is mounted at needle end 44 of barrel 40 and comprises cannula 51 and barbed arms 52A, 52B mounted to body 53 that are engageable by respective barb-engaging apertures 22 of needle-engaging means 23 in plunger 20 to facilitate retraction of needle 50 at the end of delivery of the fluid contents of syringe 10. This retraction is driven by de-compression of spring 90, as will be described in more detail hereinafter.

Referring particularly to FIG. 2, a preferred embodiment is described wherein retractable needle 50 may be fitted at needle end 44 of barrel 40 by disc member 100 that has indent 101 which co-operates with annular rib 46 on inside wall 42 of barrel 40. O-ring seal 47 is seated in annular step 48 in barrel wall 42. Body 53 of retractable needle 50 has elbows 54A, 54B that are held by annular shoulder 104 of disc member 100 until retraction of retractable needle 50.

It is also noted that according to this embodiment barbed arms 52A, 52B each comprise first barb 55A, 55B and second barb 56A, 56B. First barbs 55A, 55B provide a safety mechanism should second barbs 56A, 56B not properly engage respective barb-engaging apertures 22 to facilitate retraction of retractable needle 50. That is, first barbs 55A, 55B can engage barb-engaging apertures 22 should second barbs 56A, 56B fail to properly engage respective apertures 22.

Disc member 100 has aperture 102 with recesses 103A, 103B which allow longitudinal movement of elbows 54A, 54B therethrough to allow retraction of needle 50, as will be described in more detail hereinafter.

In an alternative embodiment, retractable needle 50 may be provided such as described in Australian Patent 731159 and United States Patent 6,083,199.

As best seen in FIG. 3A and 3B, plunger 20 further comprises plunger shaft 32 having shoulders 33A, 33B which respectively have inclined surfaces 34A, 34B

CLAIMS

1. A spring retainer for a syringe that comprises a barrel, a plunger, a spring and a retractable needle, said spring retainer comprising a housing having first and second body members adapted to releasably maintain said spring in a compressed state until rotational disengagement of said first and second body members allows decompression of said spring to facilitate retraction of said retractable needle into said barrel.

2. The spring retainer of Claim 1, wherein the first body member comprises two or more projections capable of slidably engaging respective slots in said plunger to guide rotation of said plunger in use.

3. The spring retainer of Claim 2, wherein said second body member comprises one or more recesses arranged so as to be releasably engageable by respective tabs on said first body member.

4. The spring retainer of Claim 3, wherein the second body member is adapted to be engageable by said plunger so that depression of the plunger triggers disengagement of said first body member and said second body member to thereby allow decompression of said spring.

5. The spring retainer of Claim 4, arranged so that disengagement of said first and second body members of said housing can facilitate rotation of said second body member relative to said first body member.

6. The spring retainer of Claim 5, wherein said second body member further comprises circumferential ramps arranged so that decompression of said spring forces engagement of said ramps by said tabs to facilitate rotation of said second body member relative to said first body member.

7. A syringe comprising a barrel, a plunger, a spring retainer and a spring, to which syringe a retractable needle is mountable so as to be capable of coupling with said plunger for retraction of said needle into said barrel, said spring retainer comprising a housing having first and second body members adapted to releasably maintain said spring in a compressed state until disengagement of said first and second body members allows decompression of said spring to facilitate retraction of said retractable needle into said barrel.

8. The syringe of Claim 7, wherein the first body member comprises two or more projections capable of slidably engaging respective slots in said plunger to guide rotation of said plunger in use.

9. The syringe of Claim 8, wherein said second body member comprises one or more recesses arranged so as to be engageable by respective tabs on said first body member.

10. The syringe of Claim 9, comprising plunger means for engaging respective complementary mating portions on said second body member.

11. The syringe of Claim 10, wherein the plunger means comprises two shoulders engageable with respective shoulder ramps on said second body member.

12. The syringe of Claim 11, arranged so that upon engagement between said two shoulders and respective shoulder ramps on said second body member, rotation of said shoulders selectively rotates said second body member relative to said first body member thereby disengaging said tabs from said recesses which disengages said first body member and said second body member to allow decompression of said spring.

13. The syringe of Claim 12, wherein said second body member further comprises circumferential ramps arranged so that decompression of said spring forces engagement of said ramps by said tabs to facilitate rotation of said second body member relative to said first body member.

14. The syringe of Claim 13, arranged so that rotation of said second body member is capable of assisting rotation of said plunger into a final, inoperable position.

15. The syringe of Claim 7, having said retractable needle mounted thereto, whereby in use said spring is maintained in a compressed state by said spring retainer until at or near completion of depression of said plunger when injecting material from said syringe.

16. The syringe of Claim 15, arranged so that said plunger and said retractable needle are coupled at or near completion of depression of said plunger.

17. The syringe of Claim 16, wherein disengagement of said first and second body members of said housing allows decompression of said spring, which facilitates

retraction of said plunger when said retractable needle is coupled therewith.

18. The syringe of Claim 17, arranged so that disengagement of said first and second body members of said housing can facilitate rotation of said second body member relative to said first body member.

19. The syringe of Claim 18, arranged so that rotation of said second body member is capable of assisting rotation of said plunger, when said retractable needle is coupled therewith, into a final, inoperable position.

20. The syringe of Claim 19, wherein said first body member comprises two or more projections capable of bearing against respective abutments in respective slots in said plunger to maintain said plunger in said final, inoperable position.

21. A spring retainer for a syringe substantially as described herein with reference to the accompanying drawings.

22. A syringe comprising a spring retainer substantially as described herein with reference to the accompanying drawings.